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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,704	02/16/2006	Karlheinz Bortlik	112701-706	4852

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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
11/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/568,704	BORTLIK ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) *6-8,12,14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 8/26/09 is acknowledged. Claim 13 is cancelled. Claims 1-12, 14, and 15 are pending. Claims 6-8, 12, 14, and 15 are withdrawn as they are directed toward a non-elected invention group. **Claims 1-5, and 9-11 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 112, 1st New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 1 (line 6), 9 (line 9), 10 (line 8), and 11 (line 7) recite "…without using a solvent". Although on page 7 of the specification (2nd paragraph) from the bottom, it mentions "without using a solvent", However, on page 7 of the specification, example 1 explicitly recites "50 kg of tomato puree at pH 4.3 are mixed with 100 kg of demineralized water in a batch". It is noted that water is a solvent, thus Applicant does not have support for "contains no solvent". Especially considering that a natural lycopene concentrate inherently contains water, which is a solvent by itself. Therefore, Applicant fails to provide support regarding the description of "without using a solvent". Therefore, it is not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, Applicant had possession of the "a natural

lycopene concentrate … without using a solvent" in the invention. Thus, the subject matter of "contains no solvent" is a new matter that needs to be cancelled.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, first paragraph for the reasons set forth above.

Claim Rejections –35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 10, and 11 are rejected under 35 USC § 102 (b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kawana et al (JP 08336376 A).

This is a new rejection necessitated by the Applicant's amendment filed on 8/26/09.

Kawana et al teach a production of low-viscosity tomato juice (thus a natural lycopene concentrate) (thus orally, thus a drink, thus a food, thus a liquid form, thus a dietary supplement

(100%)) is characterized by the fact that tomato is ground or cut without being heated (thus at room temperature), is directly fed into an extruder with a screen pore size of 0.01-1.0 mm (thus a solid-liquid separation) (see claim 1). Kawana et al teach this is for the purpose of stably obtaining a readily drinkable tomato juice which has approximately the same lycopene content as that of the existing product and a lower viscosity by drastically reducing the insoluble solid content in comparison to the existing product [0010]. In comparison 9, tomato was washed, sorted, and diced into 3 mm squares using a dicer. The diced material was placed in a filter cloth and fed into a juice press machine and squeezed under 5 kgf/cm2 pressure. Of the squeezed liquid (tomato juice) thus obtained, the insoluble solid content was 0.1 weight% while the lycopene content was 3 mg% (thus at least 1 mg of lycopene per g of the said concentrate) [0020] (thus a natural lycopene concentrate). Kawana et al also teach in the middle of squeezing, the cells forming the insoluble solids are ruptured mainly by being crushed; from the ruptured parts the lycopene moves into the squeezed juice. As a result, a tomato juice having approximately the same lycopene content as the existing product can be obtained. On the other hand, the cells forming the insoluble solids are simply ruptured; the insoluble solids are not made microscopically small; hence the insoluble solids, without passing through the screen, are discharged form the output of the extruder as the juice residues [0012] (thus the concentrate is isolated from fibers and other insoluble compounds by a solid-liquid separation) (see full translation attached).

As discussed above, the cited reference discloses a natural lycopene concentrate. Although the cited reference does not explicitly teach the claimed amount of protein, polysaccharide, organic acid, and lipid compounds, since the cited reference Kawana et al use the same plant

material tomato as the specification (see page 7, Example 1) to start with, and use no solvent up, thus the lycopene concentrate would inherently contain the claimed amount of each component. Consequently, the claimed composition appears to be anticipated by the references.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced method is likely to inherently possess the same characteristics of the claimed method particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed method would have been obvious to those of ordinary skill in the art with the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use for inducing photoprotection and slowing ageing of the skin (claim 10). It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

With respect to the art rejection above, please note that Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' method differs and, if so, to what extent, from that of discussed references. Therefore, with the showing of the references, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawana et al as applied to claims 1, 2, 4, 10, and 11 above, and further in view of Hamm et al (Hamm et al, Vitamin C content of thirty-six varieties of tomatoes, FASEB Journal, (1993) Vol. 7, No. 3-4, pp. A742), and Uehara et al (JP 2000229827 A).

This is a new rejection necessitated by the Applicant's amendment filed on 8/26/09.

The teachings of Kawana et al are set forth above and applied as before.

The teachings of Kawana et al do not specifically teach the claimed amount of lycopene in the concentrate, a cosmetic, or lycopene concentrate contains vitamin E or vitamin C.

As evidenced by Hamm et al, tomato contains vitamin C (see Title).

Uehara et al teach "the cosmetics are claimed. The tomato pigments may mainly comprise lycopene isolated by centrifugation of tomato preparation, microfiltration of the liquid parts, and collection of unfiltered substances by microfiltration. The cosmetics may additionally contain active oxygen scavengers, antioxidants, inflammation inhibitors, UV shields, cell activators, and/or moisturizers. A cream containing the tomato pigment was used by volunteers

to lighten skin and increase elasticity (see Abstract, the rejection is based on the Abstract, machine translation is attached).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use lycopene from tomato in cosmetic composition since Uehara et al teach tomato pigment was used by volunteers to lighten skin and increase elasticity (thus anti-aging). Since both of the inventions yielded beneficial results for using lycopene, one of ordinary skill in the art would have been motivated to make the modifications to combine the two teachings together.

Regarding the claimed amount of lycopene in the concentrate, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.);
see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or

artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of lycopene, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentrations of the claimed components are art-recognized result effective variables, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments regarding Kawaragi et al teach using an organic solvent in the reference have been fully considered and are persuasive. Therefore, the rejection has been

withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kawana et al.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655